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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,775	08/21/2003	Tamar Tennenbaum	TENNENBAUM 1C	6931

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EXAMINER
MARSCHEL, ARDIN H

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/644,775	TENNENBAUM ET AL.	
	Examiner	Art Unit	
	Ardin Marschel	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32,36,37 and 41-111* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32,36,37 and 41-111* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12 and 85-101 drawn to a method of inducing or accelerating a healing process of a skin wound comprising insulin administration to the skin wound plus at least one additional agent acting in synergy with said insulin, or, alternatively, administering only insulin classified in Class 514, subclass 2.

II. Claims 13-26, drawn to a method of inducing or accelerating a healing process of a skin wound comprising implanting into the skin wound insulin secreting cells, classified in Class 424, subclass 93.7.

III. Claims 27-32, drawn to a method of inducing or accelerating a healing process of a skin wound comprising transforming cells of the skin wound to produce and secrete insulin, classified in Class 435, subclass 440.

IV. Claims 36 and 37, drawn to a method of inducing or accelerating a healing process of a skin wound comprising transforming cells of the skin wound to produce protein kinase C, classified in Class 435, subclass 440.

V. Claims 41-51 and 102-111, drawn to a pharmaceutical composition for inducing or accelerating a healing process of a skin wound comprising insulin and at least one additional agent acting in synergy with said insulin; or, alternatively, a composition comprising only insulin; and a

pharmaceutically acceptable carrier designed for topical application; classified in Class 530, subclass 300.

VI. Claims 52-65, drawn to a pharmaceutical composition for inducing or accelerating a healing process of a skin wound comprising insulin secreting cells and a pharmaceutically acceptable carrier designed for topical application, classified in Class 435, subclass 325.

VII. Claims 66-71, drawn to a pharmaceutical composition for inducing or accelerating a healing process of a skin wound comprising a nucleic acid construct designed for transforming cells to produce and secrete insulin and a pharmaceutically acceptable carrier designed for topical application, classified in Class 536, subclass 23.1.

VIII. Claims 72-79, drawn to a pharmaceutical composition for inducing or accelerating a healing process of a skin wound comprising a nucleic acid construct designed for transforming cells to produce protein kinase C and a pharmaceutically acceptable carrier designed for topical application, classified in Class 536, subclass 23.1.

IX. Claims 80 and 82, drawn to a method of inducing or accelerating a healing process of a skin wound comprising administering to the skin wound an agent for modulating PKC production and/or activation, classified in Class 514, subclass 44.

X. Claims 81 and 83, drawn to a pharmaceutical composition for inducing or accelerating a healing process of a skin wound comprising an agent for

modulating PKC production and/or activation and a pharmaceutically acceptable carrier, classified in Class 514, subclass 44.

XI. Claim 84, drawn to a method of inducing or accelerating ex-vivo propagation of skin cells comprising subjecting the skin cells to an agent for modulating PKC production, classified in Class 514, subclass 44.

The inventions are distinct, each from the other because:

Inventions of (Groups I and V), vs (Group II and VI) vs. (Groups III and VII) vs. (Groups IV and VIII) vs. (Groups IX and X) vs. Group XI are directed to related, but distinct, inventions regarding skin care. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions of (Groups I and V), vs (Group II and VI) vs. (Groups III and VII) vs. (Groups IV and VIII) vs. (Groups IX and X) vs. Group XI have different design, mode of operation, function, and effect due to being directed to different design, mode of operation, function, and effect as follows: (Groups I and V are directed to direct insulin administration as a protein), vs (Group II and VI are directed to administering insulin secreting cells which raises the additional issue of cellular rejection as well as maintaining such cells alive to carry out their function of insulin secretion) vs. (Groups III and VII are directed to transformation of cells in a skin wound with its complications of both in-vivo transformation as well as the complex wound healing actions being carried

out by the skin which is not generally the environment under which cellular transformation is carried out) vs. (Groups IV and VIII are directed to transformation of cells in a skin wound with its complications of both in-vivo transformation as well as the complex wound healing actions being carried out by the skin which is generally not the environment under which cellular transformation is carried out) vs. (Groups IX and X are directed to modulation of PKC production and/or activation which is not carried out by any other Groups) vs. Group XI which is directed to ex-vivo skin cell propagation which is independent of the skin wound healing considerations of any of the other Groups. Therefore, an undue search burden would be required to search them together thus supporting this restriction requirement.

The inventions of Groups V and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the Group V pharmaceutical composition can be used in the materially different process of insulin therapy for diabetes treatment applied topically.

The inventions of Groups VI and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the

Group VI pharmaceutical composition can be used in the materially different process of cellular implantation of cells for diabetes treatment for insulin cellular secretion therapy of tissue culture cells for later re-introduction in a patient.

The inventions of Groups VII and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the Group VII pharmaceutical composition can be used in the materially different process of the transformation of cells in tissue culture for later therapeutic diabetes treatment via implantation of such transformed cells in a patient.

The inventions of Groups VIII and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the Group VIII pharmaceutical composition can be used in the materially different process of protein kinase C genetic transformation therapy of tissue culture cells for later introduction in a diabetes patient.

The inventions of Groups X and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another

materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the Group X pharmaceutical composition can be used in the materially different process of protein kinase C modulation therapy in a diabetes patient.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product

claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., Supervisory Patent Examiner, AU 1614, whose telephone number is (571)272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Florence Patterson, whose telephone number is (571)272-0544.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 30, 2006

Ardin H. Marschel 9/30/06

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER